

Transanal Surgery for benign tumor or early rectal cancer: state of the art and future prospects of the surgeon

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Abstract: The Parks' procedure (1973) is the most recognized conventional transanal excision (TAE). A full-thickness en-bloc excision allows an entire resection of the rectal wall with a good pathologic staging. Buess et al. published in 1988 an innovative transanal endoscopic microsurgery (TEM) allowing access to larger and higher tumors. The initial results were very encouraging with a low complication rate of 5%. Compared to TAE, this technique has proven its superiority in terms of negative resection margin, fragmentation of the specimen, postoperative morbidity and local recurrence rate. Indications are now well established. The issue is mainly based on the risk of lymph node involvement that is in particular directly related to the depth of invasion but also to others poor pathologic features. The endoscopic mucosal resection (EMR) seems to be inferior to the TEM due to a piecemeal resection and a partial staging. However the endoscopic submucosal dissection (ESD) competes with surgical techniques, especially for tumors larger than 2 cm. To date there is no recommendation in favor of ESD or TEM for the management of large benign rectal adenomas or early rectal cancer. The concept of organ preservation has emerged due to the high rate of morbi-mortality and to the functional consequences of major rectal surgery. Recent studies are trying to select good responders after neoadjuvant treatment that could benefit from a local excision. The oncologic results of recent trials such as GRECCAR II are promising with no difference in term of oncologic outcomes with the radical surgery group. But the problem remains the specific morbidity of the completion total mesorectal excision in case of poor pathologic features. A rigorous selection of patients and in particular according to the analysis of the tumor response is needed.

Keywords: Local excision; transanal endoscopic microsurgery (TEM); early rectal cancer; organ preservation; neoadjuvant chemoradiotherapy

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Introduction

Transanal surgery for rectal polyps and villous adenomas is a widely used surgical technique. Conventional transanal excision (TAE) is the most common technique, with excellent results in terms of morbidity but also recurrence rate, known as Parks' procedure (1). Technical advances have made it possible to develop new devices that facilitate surgery and that allow local excision for larger tumors and

more difficult to access. For example, transanal endoscopic operation (TEO) described by Buess *et al.* at the end of the eighties (2) offers the advantage of better visibility and better exposure.

The most used endoscopic technique, the endoscopic mucosal resection (EMR) raises the question of a piecemeal resection without a good staging. Endoscopic submucosal dissection (ESD) is an emerging endoscopic technique that

could have comparable results to transanal surgery. The lack of comparative studies leaves the debate open.

Classically, Transanal surgery was done for early rectal tumors, the important morbi-mortality rate of radical rectal surgery and impairment of quality of life led the surgeon to reconsider management and to adapt neoadjuvant strategy in order to transform major surgery in tumorectomy. Transanal endoscopic surgery could be a preferred option in selected cases.

This review describes the different procedures to perform a transanal surgery, in comparison with endoscopic techniques, and discuss indications: benign tumor including large villous polyps, early rectal cancer. We also present the concept of organ preservation in rectal cancers after neoadjuvant chemoradiotherapy and its surgical and oncologic results.

Transanal surgery: which operative technique?

Technical evolution and description of the procedures

Different technique have been described such as the Kraske (1885) transsacral approach (3,4) or the York-Mason (1977) transsphincteric technique (5) but conventional TAE of a rectal polyp or early rectal cancer is most often carried out according to the Parks' technique describing since 1973 a local excision through the anal canal (1). This technique is now well codified (6) and has long been the most used. TAE procedure consists in a full-thickness excision after locating the tumor using for example a Parks' retractor for exposition. A line is drawn all around the lesion using electrocautery, before starting the resection, to ensure a free margin of 1 cm. *En-bloc* full-thickness excision, exposing the fat, is a key point to ensure resection of the entire rectal wall for both staging and curative treatment. The main limit of the conventional TAE technique concerns highest tumors, inaccessible, generally located more than 7-8 cm from the anal verge.

Buess *et al.* published in 1988 an innovative transanal endoscopic microsurgery (TEM) technique to break free from the limits of the TAE and to avoid the invasive York-Mason approach (2). To perform TEM, a rectoscope is introduced for gas insufflation in the rectal cavity. TEM offers many advantages, with a magnified view to perform an *en-bloc* full-thickness excision. Specimen is then stretched and pinned on a cork plate for pathologic exam. The surgical outcomes of the first 140 patients were very encouraging with a low complication rate of 5% with only 1 (0.7%)

postoperative bleeding. Concerning oncologic outcomes, 12 patients had local resection only for a pT1 carcinoma and there was no local recurrence or tumour spread (7). Buess *et al.* was already describing the need for a learning curve for this difficult technique, with the implementation of a training program (8). In the original technique, Buess *et al.* suggested to close the defect with a continuous resorbable suture finished using a silver clip on the thread (2). But this point remains controversial as the defect is below the peritoneal reflexion. To date, only 2 randomized control trial (RCT) (9,10) and 5 retrospective comparative studies (11-15) compared outcomes according to the closure of the rectal wall. *Table 1* summarizes these results. There appears to be a trend towards closing the defect in terms of postoperative complications but the result was not confirmed in the RCTs. A recent meta-analysis found no significant difference about morbidity, postoperative infection, postoperative bleeding rate and reintervention rate (16). So the discussion about closing the rectal wall after TEM is still open and no recommendation could be made. A technical issue that could arise with TME and didn't exist with the TAE is the occurrence and management of peritoneal perforation, in 1.7% to 15% of cases (17-21), particularly for anterior and upper rectal tumors. However, this complication should not cause the technique to be discussed because its laparoscopic suture is feasible as showed by Mege *et al.*, without an increase in postoperative morbidity rate if diagnosis was made during the procedure (18).

Comparison of operative techniques

Compared to TAE, TEM has proven its superiority (*Table 2*). Comparatives studies found advantages for TEM in terms of negative resection margin, fragmentation of the specimen (no *en-bloc* resection), postoperative morbidity and local recurrence rate (22-25). Clancy *et al.* published a meta-analysis with these data (26). They also demonstrated the superiority of TEM for negative microscopic margin rate (P<0.001), specimen fragmentation rate (P<0.001) and recurrence (P<0.001).

Different devices are used to perform TEM, with a better visualization and precision than TAE. Buess *et al.* initially described a reusable rectoscope still in use today: TEO® platform (Karl Storz, Tuttlingen, Germany) (2). Several disposable materials also allow TEM through a single-incision laparoscopic surgery port, called Transanal mini-invasive surgery (TAMIS) (27). The two most commonly used are the single-incision assisted laparoscopic surgery

Table 1 Results of studies evaluating the defect closure after transanal excision

| Publication (ref) | Population (n) | Method | Defect Closed (n) | Endpoint | Results if defect closed (%) | Results if defect open (%) | p |
|-------------------------------------|----------------|---------------|-------------------|----------------------------------|------------------------------|----------------------------|--------------------|
| Brown, Surg Endosc 2017 (11) | 341 | Retrospective | 236 | 30-day complications | 8.5 | 19 | 0.003 |
| Brown, Colorectal Dis 2019 (10) | 50 | RCT | 28 | Postoperative pain day 1 – 3 – 7 | 2.8 – 2.8 – 2.8 | 2.6 – 2.1 – 1.7 | 0.76 – 0.23 – 0.09 |
| Chan, Surg Endosc 2019 (12) | 297 | Retrospective | 183 | Recurrence | 9.3 | 21.3 | 0.003 |
| Chan, Surg Endosc 2019 (12) | 297 | Retrospective | 183 | R1 rate | 6 | 10 | <0.001 |
| Hahnloser, Colorectal Dis 2015 (13) | 75 | Retrospective | 40 | Postoperative complications | 13 | 17 | ns |
| Lee, Dis Colon Rectum 2018 (15) | 220 | Retrospective | 110 | 30-day complications | 12 | 15 | 0.432 |
| Lee, Dis Colon Rectum 2018 (15) | 220 | Retrospective | 110 | Postoperative bleeding | 3 | 9 | 0.045 |
| Noura, Mol Clin Oncol 2016 (14) | 43 | Retrospective | 21 | Postoperative complications | 33.3 | 4.5 | 0.02 |
| Ramirez, Colorectal Dis 2002 (9) | 40 | RCT | 21 | Postoperative bleeding | 4.8 | 10.5 | ns |

Table 2 Results of comparative studies evaluating outcomes of TAE and TEM

| Publication (ref) | R1 (%) | | | Specimen Fragmentation (%) | | | LR (%) | | | Complication (%) | | |
|------------------------------------|--------|-----|--------|----------------------------|-----|--------|--------|------|--------|------------------|-----|--------|
| | TAE | TEM | p | TAE | TEM | p | TAE | TEM | p | TAE | TEM | p |
| Christoforidis, Ann Surg 2009 (22) | 16 | 2 | 0.017 | – | – | – | 29.1 | 15.4 | 0.108 | 22 | 29 | 0.414 |
| de Graaf, Colorectal Dis 2011 (23) | 50 | 12 | <0.001 | 23.8 | 1.4 | <0.001 | 28.7 | 6.1 | <0.001 | 10 | 5.3 | <0.001 |
| Han, World J Surg 2017 (24) | 13.9 | 4.2 | 0.039 | 9.7 | 1.4 | 0.029 | 5.6 | 0 | 0.243 | 11.1 | 8.3 | 0.39 |
| Moore, Dis Colon Rectum 2008 (25) | 29 | 10 | 0.001 | 35 | 6 | <0.001 | 24 | 4 | 0.004 | 17 | 15 | 0.69 |

TAE, transanal excision; TEM, transanal endoscopic microsurgery; R1, positive microscopic margins; LR, local recurrence.

(SILS) Port (Covidien, United States) and the GelPOINT Path Transanal Access Platform (Applied Medical, United States). There is no recommendation for preferential use of any of the devices. None of the techniques have proven to be superior for the quality of the surgical resection (21,28). TEO and TAMIS seem feasible depending on the surgeon's habits. Indeed, these surgical techniques require

rigorous learning curve to achieve quality oncologic results, in particular the rate of positive margin (R1). Lee *et al.* published an observational cohort studies showing that TAMIS requires a minimum of 14–24 cases to reach an acceptable R1 resection rate (29).

Technical and material advances have made it possible to increase the feasibility of transanal surgery.

Transanal surgery for benign tumor or early rectal cancer

Rectal polyps and villous tumors

Some indications of transanal surgery for rectal tumors are now well established. Concerning benign tumors, TEM has the advantage of a full-thickness resection compared with EMR, which generally performs a piecemeal resection, especially for large villous tumors that have an important risk of malignant transformation (30), up to 33% of unsuspected cancer for giant villous adenomas of the rectum (31). The difficulty in these cases of large villous tumors remains the preoperative evaluation even with careful clinical examination and MRI. For benign adenomas and villous tumors, TEM achieve a complete staging contrary to the EMR, with good surgical and oncologic outcomes. A large Italian multicentric cohort of 588 patients with benign tumor reported a global morbidity rate of 11.4%, no postoperative mortality, a percentage of local recurrence of 4.3% with a median operative time of 105 min (32). Concerning villous tumors, Pigot *et al.*, in a French series of 207 consecutive patients with large rectal villous adenomas (mean size of resected tumor: 5.4 cm), showed excellent results with a recurrent rate of 3.6% with a mean follow-up of 74 months. They noticed that specific recurrence-free probability was 99.5 percent at one year, 96 percent at five years, and 95 percent at ten years. (30).

Primary surgery for early rectal cancer

Management of early rectal cancer that can be discovered on the pathologic report or diagnosed at the beginning of treatment must take into account many parameters in particular the risk of lymph node involvement. Depth invasion of the rectal wall need to be described. The rate of lymph node involvement varies from 0 to 15% for T1 tumors and from 16 to 28% for T2 (33). Kikuchi classification for pT1 rectal adenocarcinoma consists in the division of the submucosal layer in three parts: sm1, sm2 and sm3 (34) with a lymph node involvement risk of 0–3% for sm1, 8–10% for sm2, and 23–25% for sm3 (35). The other additional risk factors increasing the rate of lymph node involvement that are details in the recent French Guidelines for the managements of rectal cancer are poor-differentiated tumors, vascular or lymphatic emboli and tumor budding (36–38). Bach *et al.* described a multivariable analysis to determine predictive factors of local recurrence: depth of invasion, diameter of the tumor and intramural lymphovascular

invasion (39). Tumor size and circumference are still debating (33) but are considered to be factors associated with technical difficulty as well as height (upper rectum) (19,40). Positive resection margin is usually considered as a pejorative factor but no study demonstrated the need to achieve a complete lymphadectomy instead of a new local excision (33,36).

A completion proctectomy with total mesorectal excision (cTME) should be discussed for patients with poor prognosis criteria due to lymph node involvement risk and local recurrence rate. In practice, local excision for T1sm1 without further risk factors is acceptable in term of nodal disease and local recurrence but a cTME should be discussed since there are associated risk factors or for T1sm2 or T1sm3 tumors.

Surgical outcomes after TEM for benign tumors or early rectal cancer (with no other treatment, excluding all neoadjuvant therapy) in large series are presented in *Table 3* (20,32,39–44). Perioperative mortality is closed to 0 and major complication rate, which correspond to stages III–IV–V of the Dindo-Clavien classification (45), varies to a maximum of 3.8%.

With such good morbi-mortality results, it is difficult to envisage alternative management for these tumors. The TREND study was a retrospective analysis collecting data from patients treated with TEM or EMR for a large rectal adenoma (>2 cm). Early recurrence rate was 10.2% in the TEM group and 31.0% in the EMR group ($P < 0.001$) (46).

Management of small rectal cancer: surgical resection or ESD?

ESD is an emerging endoscopic treatment, which competes with surgical techniques due to its proven superiority over the EMR in terms of *en-bloc* and curative resections and local recurrence rate, especially for tumors larger than 2 cm (47). Indeed, this technique allows mucosal and also sub-mucosal resection and avoids piecemeal resection contrary to EMR. But ESD is a complex procedure, responsible for a longer operative time (47). A debate has been developed between surgeons and endoscopists particularly with regard to the operative time, but also to the cost. The first retrospective study published by Park *et al.* in 2012 comparing ESD and TEM included adenomas with high grade dysplasia or early rectal cancer (T1) (48). *En-bloc* resection (96.7% vs. 100%, $P = 0.476$) and R0 resection (96.7 vs. 97, $P = 1$) rates did not differ between ESD group and TEM group respectively but procedure time for the

Table 3 Surgical outcomes after transanal surgery for benign tumor or early rectal cancer without any neoadjuvant treatment

| Publication (ref) | Population (n) | Overall perioperative morbidity (%) | Minor complications (%) | Major complications (%) | Perioperative mortality (%) | Median (range) LOS (d) | Median (range) operative time (min) |
|-----------------------------------------|----------------|-------------------------------------|-------------------------|-------------------------|-----------------------------|------------------------|-------------------------------------|
| Baatrup, Int J Colorectal Dis 2007 (41) | 142 | 30.2 | 27.4 | 2.8 | 0.7 | 3 (2–36) | – |
| Bach, Br J Surg 2009 (39) | 487 | 14.9 | – | – | 1.4 | – | – |
| Guerrieri, Dig Liver Dis 2006 (32) | 588 | 9.4 | 8.2 | 1.2 | 0 | 3.5 | 105 |
| Khoury, Surg Endosc 2014 (40) | 99 | 10 | 9 | 1 | 0 | 2 (1–17) | 70 (35–240) |
| Kumar, Dis Colon Rectum 2013 (20) | 325 | 10.5 | – | – | 0.3 | 0.54 | 119.5 |
| Maleskar, Surg Endosc 2007 (42) | 52 | 29.8 | 26 | 3.8 | 0 | 2 (1–12) | 90 (20–150) |
| Ramirez, Ann Surg 2009 (43) | 173 | 14.5 | 11 | 3.5 | 0.58 | 4 (2–30) | – |
| Said, Surg Endosc 1995 (44) | 260 | 3.4 | 0 | 3.4 | 0.4 | – | – |

Minor complications, Dindo-Clavien I-II; Major complications, Dindo-Clavien III-IV-V; LOS, length of stay.

ESD group was shorter than that for the TEM group (mean: 84.0 min *vs.* 116.4 min, $P=0.023$). There were few patients in the study (only 30 ESD and 33 TEM). Kawaguti *et al.* published the second retrospective comparative study including 11 ESD and 13 TEM (49). There was no difference in the *en-bloc* resection rates with free margins: 81.8 % *vs.* 84.6 % ($P=0.40$) in ESD group and TEM group respectively. The operative time was also comparable ($P=0.69$). Finally a systematic review published by Arezzo *et al.* in 2014 with 21 series (but no comparative studies) for a total of 2,077 patients showed a higher *en-bloc* resection ($P<0.001$) and RO ($P<0.001$) rates in the benefit of TEM with no difference in the postoperative complications rate (50). So there is a clear lack of quality comparative studies on the subject and there is no consensus for the management of the large benign rectal adenomas or early rectal cancer. In this case, the European Association for Endoscopic Surgery (EAES) recommends that ESD and TEM are the two established techniques to perform local excision (51). A French prospective non-randomized study is in progress to compare ESD with TEM for early rectal cancer and rectal adenomas for R0 resection rate and the cost-effectiveness ratio: MUCEM-GRECCAR 13 (ClinicalTrials.gov Identifier: NCT02885142).

Transanal surgery for rectal cancer following neoadjuvant treatment

Rational

Radical surgery for rectal cancer is based on total

mesorectal excision (TME) (52). This management is well codified by oncologic quality criteria (36) but presents some challenges for the surgeon and the patient. First, sphincter preservation is a major issue that could be difficult for ultra-low rectal tumors. Even when sphincter preservation is possible, functional outcomes could be altered, in particular anal continence, by factors such as the type of anastomosis or the height of the tumor and so the height of the anastomosis (53). Sexual and urinary dysfunctions are also major complications for the patient, often underestimated, becoming more and more of a quality of life concern with an increasing number of studies evaluating prevalence, risk factors and management (54). The third key point for the discussion concerns anastomotic complications after TME. Pelvic abscess and anastomotic leakage rates remain high, up to 19% in large series (55–57). Locally advanced rectal cancer are treated first with neoadjuvant treatment (NAT): the reference is a chemoradiotherapy decreasing local recurrence rate (58,59). Tumor response after NAT need to be evaluated and it is a key point for surgical management. Pathologic complete response (pCR) rate after NAT and resection, which corresponds to pT0N0 tumors, ranges from 15 to 29% in recent RCTs (57,60,61).

So the concept of organ preservation has emerged (62): local excision after NAT is a treatment for residual N0 tumors (subcomplete or complete response) but it could be also a macrobiopsy to confirm staging and to adapt final management (63). It is now recognized that there is a correlation between the tumor response and the nodal status response (63). For pT0 and pT1 tumors, Rullier and Vendrely underlined that the 7% risk of positive lymph

Table 4 Results of studies evaluating outcomes of local excision following neoadjuvant treatment

| Publication (ref) | Method | Population (n) | cTNM | pCR (%) | LRR n (%) | DR n (%) | Median Follow-up (months) |
|-----------------------------------------|---------------------------|----------------|----------|---------|-----------|----------|---------------------------|
| Bujko, Radiother Oncol 2009 (65) | RCT | 47 | T1-3N0 | 41 | 3 (6.4) | 1 (2.1) | 14 |
| Bujko, Radiother Oncol 2013 (66) | RCT | 89 | T1-3N0 | 43.8 | 13 (14.6) | 6 (6.7) | 24 |
| Garcia-Aguilar, Lancet Oncol 2015 (69) | Prospective, Phase II | 77 | T2N0 | 44 | 3 (3.9) | 5 (6.5) | 56 |
| Lezoche, Br J Surg 2012 (67) | RCT | 50 | T2N0 | 28 | 4 (8) | 2 (4) | 115 |
| Perez, Dis Colon Rectum 2013 (70) | Retrospective | 27 | T2-3N0-1 | 11.1 | 4 (14.8) | 5 (18.5) | 15 |
| Pericay, Clin Transl Oncol 2016 (71) | Prospective observational | 15 | T2-3N0 | 26.7 | 0 (0) | 1 (6.7) | 38 |
| Pucciarelli, Dis Colon Rectum 2013 (72) | Prospective, Phase II | 63 | T2-3N0-1 | 30.2 | 2 (3.2) | 3 (4.8) | 36 |
| Rullier, Lancet 2017 (64) | RCT | 74 | T2-3N0-1 | – | 4 (5.4) | 9 (12.2) | 36 |
| Smart, Br J Sur 2016 (73) | Prospective | 62 | T1-2N0 | 32.3 | 4 (6.4) | 4 (6.4) | 13 |
| Verseveld, Br J Surg 2015 (74) | Prospective | 47 | T1-3N0 | 44.7 | 4 (8.5) | 1 (2.1) | 17 |
| Wawok, Radiother Oncol 2018 (68) | RCT | 51 | T1-3N0 | 47 | 11 (21.6) | 6 (11.8) | 104 |
| TOTAL | – | 602 | – | – | 52 (8.6) | 43 (7.1) | – |

cTNM, evaluation stage before NAT; pCR, pathologic complete response (=pT0); LRR, loco regional recurrence; DR, distant recurrence; RCT, randomized controlled trial.

nodes must be balanced with the 2% to 4% of operative morbidity in radical surgery for rectal cancer (63).

Oncologic results

Long-term oncologic results need to be discussed for patients treated with neoadjuvant chemoradiotherapy followed by local excision. The recent results of the French multicenter phase III RCT GRECCAR 2, comparing local excision and TME after neoadjuvant chemoradiotherapy in good responders, showed a 3-year loco-regional recurrence rate of 5.4% and 3-year distant recurrence rate of 12.2% in the local excision group in the intention-to-treat population. There was no difference between the groups in term of local recurrence, distant recurrence, disease-free survival and overall survival (64). Five RCTs (64-68) and 6 non-randomized studies (69-74), aiming to analysis oncologic outcomes in patients treated with local excision after NAT, are listed in *Table 4*. Loco-regional recurrence rate must be carefully analyzed according to the methods of the studies (for example when the analysis is retrospective). But the GRECCAR 2 (64), the American ACOSOG Z6041 (69) or the Italian multicenter phase II trial (72) found interesting results for selected patients (good responders after NAT or initially small tumors). It is also important to notice that pCR rate for small tumors treated with NAT

can reach 47%. Long-term results are presented in *Table 5*, in comparison to the few studies that report oncologic outcomes and long-term survival of local excision without any NAT, also in the case of benign tumors. Concerning studies evaluating long-term results after NAT, three-year disease-free survival varies from 78% to 91%, depending on the initial T and N of treated tumors, which is an acceptable oncologic outcome in these cases. In these papers, patients treated are good responders with a good oncologic prognosis. The other studies, with surgery first, usually include smaller tumors and present similar loco-regional recurrence rate and oncologic outcomes. The *Table 5* results support the possibility to perform local transanal surgery for certain well-selected rectal cancers after NAT (12,44,64,67,69,71,72,75,76).

Morbidity

Overall peri-operative morbidity rate following local excision after NAT ranges from 8.8% to 58.4% in different series (67,69,74,76-78). Very few studies have focused on the comparison of morbi-mortality rates with or without NAT. Marks *et al.*, in 2009, in a study with 62 patients, found an overall morbidity rate of 33% for the NAT group and 5.3% for the non-NAT group (P<0.05). The wound complication rate was also in favor of the non-NAT group

Table 5 Long term results of local excision with or without neoadjuvant treatment

| Publication (ref) | Population (n) | NAT (n) | Cancer (%) | Benign (%) | R1 (%) | LRR (%) | 3y-DFS (%) | 5y-DFS (%) | 3y-OS (%) | 5y-OS (%) |
|-----------------------------------------|----------------|---------|------------|------------|--------|---------|------------|------------|-----------|-----------|
| Chan, Surg Endosc 2019 (12) | 297 | 0 | 0 | 100 | 5.8 | 13.8 | – | 73.1 | – | – |
| Garcia-Aguilar, Lancet Oncol 2015 (69) | 77 | 77 | 100 | 0 | 1.3 | 4 | 88.2 | 79.3 | 94.8 | 90.3 |
| Lezoche, Br J Surg 2012 (67) | 50 | 50 | 100 | 0 | 0 | 8 | – | 88 | – | 80 |
| Ondhia, Colorectal Dis 2019 (75) | 141 | – | 33.3 | 66.7 | 8.5 | 4.7 | – | 82.9 | – | 87.9 |
| Pericay, Clin Transl Oncol 2016 (71) | 15 | 15 | 100 | 0 | – | 0 | 91 | – | 73 | – |
| Pucciarelli, Dis Colon Rectum 2013 (72) | 63 | 63 | 100 | 0 | – | 3.2 | 91 | – | 91.5 | – |
| Rullier, Lancet 2017 (64) | 74 | 74 | 100 | 0 | 0 | 5 | 78 | – | 92 | – |
| Said, Surg Endosc 1995 (44) | 260 | 0 | 0 | 100 | – | 6.5 | – | 93 | – | – |
| Shin, Radiat Oncol J 2016 (76) | 34 | 34 | 100 | 0 | 2.9 | – | 97.1 | – | 100 | – |

NAT, neoadjuvant treatment; DFS, disease-free survival; OS, overall survival.

($p < 0.015$) (79). Two other studies reported results comparing morbidity rate with and without NAT: there was no significant difference (80,81).

The main problem for rectal cancer treated with local excision is the existence of poor prognostic factors requiring a cTME. Indeed, a second surgery in the early postoperative period exposes the surgeon to surgical difficulties due to inflammation and fibrosis, with a risk of increased anastomotic failure but also poorer oncologic outcomes. In the GRECCAR 2 trial, there was no superiority of local excision over TME because the primary endpoint was a composite outcome including morbi-mortality. The outcomes in the local excision group were more complicated due to the specific morbidity rate after cTME, concerning 38% of the cases. Major morbidity rates (Dindo III-IV) was 46% in patients treated with cTME, and only 12% in the local excision group without cTME and 22% in the TME group ($P = 0.0031$) (64). Four case-matched studies and one retrospective cohort study have compared surgical, pathologic and oncologic outcomes between local excision plus cTME and primary TME (pTME) (82-86). Results are summarized in *Table 6*. There is a trend in favor of pTME in terms of overall morbidity (for example anastomotic complications), quality of mesorectal excision, definitive stoma and operative time. The second option after local excision following NAT with poor pathologic prognostic factors is a strict surveillance with salvage TME when a local regrowth or recurrence is diagnosed. However, here again TME seems to be associated with more R1 resection and local re-recurrences (87).

Local excision after NAT for rectal cancer is clearly feasible with increasingly controlled outcomes. But a rigorous selection of cases and in particular according to the analysis of the tumor response is needed. The tools for interpreting this response (MRI, biomarkers) are constantly being improved and will allow the surgeon to adapt the surgical strategy.

Conclusion and future prospects

Management of rectal cancer is in permanent evolution (88). The intensification of the neoadjuvant treatment, called Total Neoadjuvant Therapy (TNT) which used induction or consolidation chemotherapy could increase tumor response (with a higher rate of pCR) (89). This high rate of tumoral response should help surgeon to adapt the strategy in order to decrease surgical morbidity and to increase quality of life. A French prospective multicentric phase III randomized trial is in progress investigating this strategy (GRECCAR 12): the aim is to increase organ preservation in rectal cancer adding induction Folfirinox before chemoradiotherapy (ClinicalTrials.gov Identifier: NCT02514278).

Another approach to preserve the rectum consists in local excision followed by adjuvant treatment such as chemoradiotherapy in case of poor pathologic features. It could avoid cTME and it seems to be feasible oncologically for selected tumors. The risk-benefit balance with the morbidity of cTME should be taken into account (90-92). The TESAR trial is investigating this strategy and will try

Table 6 Comparative studies evaluating surgical, pathologic and oncologic outcomes after cTME and pTME

| Publication (ref) | Method | cTME/ pTME (n) | Morbidity cTME/pTME (%) | Anast Compl cTME/pTME (%) | R1 cTME/ pTME (%) | Defect cTME/ pTME (%) | Definitive stoma cTME/ pTME (%) | LRR cTME/ pTME (%) | Operative time* (min) cTME/pTME | LOS* (day) cTME/pTME |
|-----------------------------------------|--------------------|-------------------|-------------------------------|------------------------------------|----------------------------|-----------------------------|---------------------------------------|--------------------------|---------------------------------------|-------------------------|
| Coton, Colorectal Dis 2019 (82) | Case-matched study | 41/41 | 48.8/31.7 | 17/14.6 | 2,4/0 | 17/4.8 | 9.8/4.9 | – | 315 / 275* | 14 /13 |
| Junginger, World J Surg Oncol 2019 (83) | Retrospective | 46/– | – | – | – | – | – | 6.5 | – | – |
| Levic, Tech Coloproctol 2013 (84) | Case-matched study | 25/25 | 52/52 | 4/4 | – | 40/14 | 56/56 | 0/8 | 165/193 | 10/10 |
| Morino, Surg Endosc 2013 (85) | Case-matched study | 17/34 | 11.8/23.5 | – | 0/0 | 0 | 41.2/11.7* | – | 206 /188* | 10.9/11.1 |
| Piessen, Colorectal Dis 2012 (86) | Case-matched study | 14/25 | 64.3/32 | 42.8/8* | 14.3/4 | 71/4* | 28.6/28 | – | 305 /279 | 14 / 14 |

* , Mean ± SD or median (range). cTME, completion Total Mesorectal Excision; pTME, primary Total Mesorectal Excision; Defect (cTME or pTME), Incomplete mesorectal excision; LRR, loco regional recurrence.

to demonstrate the safety of adjuvant chemoradiotherapy after local excision (93).

In the near future, robotic devices could help local excision in selective difficult cases in particular within the limit of the TEM (94,95) but also with the help of a dedicated single port system (96).

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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